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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,595	07/05/2000	Leena Peltonen	VOSS1130	1041

7590 06/30/2004

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EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,595	PELTONEN ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,30,32-34,36-38,41-43,45-53,55-62,66 and 68 is/are pending in the application.
- 4a) Of the above claim(s) 49-53 and 55-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,30,32-34,36-38,41-43,45-48,62,66 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12-3-2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of claims

Claims 29-30, 32-34, 36-38, 41-43, 45-53, 55-62, 66 and 68 are pending.

Applicant's response filed 7 June 2004, which amends claims 29-30, 32, 34, 36-38, 41, 43, 45, 48, 54 and 66, cancels claims 31, 35, 44, 63-65 and 67, and add claim 68 has been entered. Also, applicants' request (filed 7 June 2004) for extension of time of three months has been entered.

Note that claims 1-28 and claims 39-40 were canceled by applicants' amendment filed 8 March 2000 and amendment filed 22 September 2003, respectively, and that claims 49-53 and 55-61 are withdrawn from consideration (see the previous Office action mailed 26 March 2003). Therefore, the pending claims 29-30, 32-34, 36-38, 41-43, 45-48, 62, 66 and 68 are examined in this Office action.

Please note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

IDS

The references lists in IDS filed 3 December 2003 have been received and considered.

Claim Rejections - 35 USC §112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 42 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 and 45 are indefinite because of depending from the cancelled claim 35. The dependent claims 46 and 47 are also rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe (i) any sub-sequence (i.e., fragments) that consists of between at least 21 contiguous nucleotides and 2245 contiguous nucleotides of SEQ ID NO:1, wherein the nucleotide sub-sequence consisting of "21 contiguous nucleotides" gives rise to ~ 0.94% sequence identity to 2245 nucleotides of the full-length SEQ ID NO:1 (claim 41); and (ii) any sub-sequence (i.e., fragments) that consists of between at least 21 contiguous nucleotides and 1656 contiguous nucleotides of SEQ ID NO:6, wherein the nucleotide sub-sequence consisting of "21 contiguous nucleotides"

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gives rise to ~ 1.26% sequence identity to 1656 nucleotides of the full-length SEQ ID NO:6.

The current claim language encompasses a large number of the polynucleotide variants that are both structurally and functionally deviated from the claimed full-length APECED polynucleotide of SEQ ID NOs:1 and 6. The instant claim recites that the APECED polynucleotide encoding the polypeptide which functions as a transcription factor or transcription-associated factor. Yet, there are no factual evidence or/and sufficient teaching the subsequence having only 21 nucleotides has the same functional of the full-length SEQ ID NO:1 or SEQ ID NO:6. Thus, applicants are therefore not in possession of polynucleotide subsequence having length between 21 and 2245 nucleotides (SEQ ID NO:1) or between subsequence having length between 21 and 1656 nucleotides (SEQ ID NO:6).

Applicant has disclosed only the full-length polynucleotides of SEQ ID NOs:1 and 6; therefore, the skilled artisan cannot envision all the contemplated nucleotide sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993).

Making changes from sub-sequence comprising from 21 nucleotides (or a portion or fragment) to the full-length SEQ ID NO:1 or 6 does not provide maintaining the same three-dimensional structure of the polypeptide encoded by the polynucleotide thereof as by the 100% identity over that of the full-length SEQ ID NO:1 or 6 polynucleotide.

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The Guidelines for the Examination of Patent Application Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that the applicants were in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of the polynucleotide variants or/and mutants to describe its use in testing for a carriership for APECED or for a corresponding disease state (see page 1). Thus, Applicant was not in possession of the claimed polynucleotide variants/mutants or sub-sequences of the SEQ ID NO:1 or SEQ ID NO:6. *See University of California v. Eli Lilly and co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicants' response to the rejection under 35 USC, the first paragraph

The response filed 7 June 2000 asserts that the sub-sequences (fragments) from SEQ ID NO:1 and SEQ ID NO:6 nucleotide sequences have been disclosed in the specifications (see the response at page 13, the 2nd to the last paragraph), and that

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applicants were in possession of the invention of claim 41. The applicants' argument is found to be not persuasive because the specification does not describe and teach any subsequence having at least 21 contiguous nucleotide which has the same biological functions (e.g., transcriptional regulation activity), and because the reason set forth in the above-stated rejection; and thus, applicants are not in possession of the invention of claim 41.

Note that the rejection under 35 USC 102 and 103 are withdrawn in light of the applicants' amendment to the claims.

Conclusion

Claims 41-42 and 45-47 are not allowed. Claims 29-30, 32-34, 36-38, 43, 48, 62, 66 and 68 are free from the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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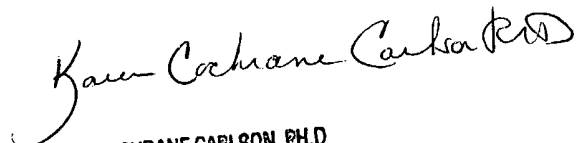
advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (571) 272-0951. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Samuel Wei Liu, Ph.D.

June 23, 2004


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER